UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2738
This Document Relates To All Cases	

DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT, LLC'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF DRS. DAVID KESSLER, LAURA PLUNKETT, WILLIAM SAGE AND GEORGE NEWMAN

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Plaintiffs seek to have four expert witnesses—Drs. David Kessler, Laura M. Plunkett, William Sage and George E. Newman—offer various opinions on legal, regulatory, marketing and talc safety matters. These opinions—none of which were addressed by the Court's prior Rule 702 ruling—should be excluded in full for multiple reasons.

First, Drs. Kessler, Plunkett, Sage and Newman seek to offer subjective narrative summaries of straightforward litigation documents and deposition transcripts in the guise of expert testimony. Such recitations of record evidence do not qualify as expert testimony because jurors are equipped to review the evidence and interpret it for themselves.

Second, Drs. Kessler, Plunkett and Sage's reports are replete with impermissible legal opinions, including citations to federal laws and FDA regulations, followed by bottom-line conclusions about whether the J&J defendants complied with those standards. These opinions are not proper expert testimony, as courts have previously recognized in excluding opinions from Drs. Kessler and Plunkett, including in other talc litigation.

Third, Drs. Kessler, Plunkett, Sage and Newman repeatedly seek to divine the J&J defendants' state of mind—i.e., what they knew, intended and when. It is well established that such opinions fall outside the scope of permissible expert testimony because jurors are fully capable of determining the parties' knowledge

and intent based on evidence presented at trial.

Fourth, Drs. Kessler, Plunkett, Sage and Newman offer variations of their subjective opinion that the J&J defendants acted unethically and failed to adhere to certain internal ethics policies. However, an expert's subjective gloss on what is reasonable conduct for a pharmaceutical company is not tethered to any discernible methodology and is inherently unreliable. Moreover, speculative claims about ethical standards are irrelevant to the product-liability issues in this litigation, do not assist the fact finder, and are unduly prejudicial and confusing under Rule 403.

Fifth, Dr. Newman's marketing opinions—that the J&J defendants misled consumers regarding the safety of talc—are separately inadmissible because they are not the product of any methodology, let alone a reliable one. Dr. Newman essentially seeks to interpret internal J&J documents, but he does not provide any real expert analysis—e.g., an analysis of empirical data—that would assist the jury, as required by Rule 702.

Sixth, while Dr. Plunkett (a pharmacologist turned career litigation expert) and Dr. Sage (a non-practicing anesthesiologist and current professor) offer a smattering of opinions regarding the alleged relationship between cosmetic talc and ovarian cancer, those opinions are not the product of a reliable methodology. Dr. Plunkett purports to have performed a "risk assessment" of the relationship between cosmetic talc and ovarian cancer, but such an exercise requires a scientist

to first determine whether a particular toxin is causally linked to the health effect being studied, which Dr. Plunkett expressly disclaimed doing in this litigation. And Dr. Sage's ruminations appear to be based on what other experts are claiming about cosmetic talc, which is mere parroting that does not satisfy the requirements of Rule 702.

Finally, Dr. Kessler's opinions that defendants' talc products contained asbestos and that the talc industry did not adequately test for purported asbestos and his claims regarding the geological formation of asbestos in talc mines far exceed the scope of his relevant expertise. Dr. Kessler's background and experience in FDA regulations and practices do not imbue him with specialized knowledge in geology, which is why he effectively conceded that he is not an expert on these topics.

For all of these reasons, discussed further below, the Court should exclude in their entirety the opinions being offered by Drs. Kessler, Plunkett, Sage and Newman.

BACKGROUND

A. David Kessler, M.D., J.D.

Dr. Kessler is a former commissioner of the U.S. Food & Drug Administration ("FDA") and now a frequent litigation expert in pharmaceutical litigation, virtually always for plaintiffs. In every litigation in which Dr. Kessler has been asked to opine on the adequacy of a label, he has claimed that the label is

inadequate.[1] In 2020, he confirmed that he has never served or testified on behalf of a defendant manufacturer in a personal injury case.[2] These statistics highlight the one-sided nature of Dr. Kessler's approach to product-liability litigation.

Dr. Kessler seeks to utilize his FDA background as a platform from which to testify on several subjects that are improper topics of expert testimony. Notably, courts have excluded Dr. Kessler from offering improper "expert" testimony, including opinions that purport to tell jurors that a defendant "violated the law." *In re Prograf Antitrust Litig.*, No. 11-02242, 2014 WL 7641156, at *1-2 (D. Mass. Dec. 23, 2014); *see also King v. DePuy Orthopaedics, Inc.*, No. 23-00196, 2023 WL 5624710, at *3 (D. Ariz. Aug. 31, 2023) ("[T]he court finds that Dr. Kessler's opinion that DePuy failed to adequately warn is not proper testimony."). But that is precisely what Dr. Kessler seeks to do here, telling jurors that the J&J defendants violated ***legal*** standards by failing to "substantiate the safety of their talcum powder products."[3] Indeed, he goes so far as to claim that J&J's talcum powder products were contaminated with asbestos and therefore "adulterated"

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[1] (*See* Trial Tr. 136:16-137:19, *Russell v. Janssen Pharms., Inc.*, No. 150500362 (Pa. Ct. Com. Pl. Apr. 12, 2018) (Ex. 1 to Decl. of Jessica Davidson ("Davidson Decl.")).)

[2] (*See* Dep. of David A. Kessler 240:9-19, *In re Davol Inc./C.R. Bard, Inc. Polypropylene Hernia Mesh Prod. Liab. Litig.*, MDL No. 2846 (S.D. Ohio, Jan. 31, 2020) (Ex. 2 to Davidson Decl.).)

[3] (Am. Rep. of David A. Kessler ("Kessler Am. Rep.") §§ III- IV, Nov. 15, 2023 (Ex. 3 to Davidson Decl.); *id.* ¶¶ 106, 154, 232.)

under 21 U.S.C. § 361.[4] Dr. Kessler also seeks to opine on J&J's state of mind by summarizing and quoting cherry-picked internal documents and testimony that jurors can comprehend as they see fit.[5]

B. Laura Plunkett, Ph.D.

Dr. Plunkett is a litigation pharmacologist who also purports to be a toxicologist.[6] At her deposition, she claimed that she is not "doing a causation opinion."[7] Nonetheless, she purports to conduct a so-called "risk assessment" that expressly calls for a determination of causation and involves her review and discussion of select epidemiology.[8]

The other opinions Dr. Plunkett wants to offer in this case do not arise from the fields of pharmacology or toxicology. Instead, Dr. Plunkett intends to offer opinions about the propriety of defendants' business practices, their state of mind and the legal and regulatory regime governing cosmetics, including whether defendants complied with labeling requirements for talc-based cosmetics. Based

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4 (*Id.* ¶ 139.)

5 (*See, e.g.*, *id.* § VI.B (J&J "had concerns regarding asbestos and the safety of its product").)

6 (3d Am. Rep. of Laura M. Plunkett ("Plunkett 3d Am. Rep.") ¶ 1, May 28, 2024 (Ex. 4 to Davidson Decl.).)

7 (Dep. of Laura M. Plunkett ("12/21/23 Plunkett Dep.") 92:7-13, Dec. 21, 2023 (Ex. 5 to Davidson Decl.).)

8 (*See, e.g.*, Plunkett 3d Am. Rep. ¶¶ 72-74.)

on her summary of internal company records and testimony, Dr. Plunkett opines that talc-based body powders should carry an ovarian cancer warning.[9]

Notably, courts have repeatedly excluded Dr. Plunkett's opinions as usurping the province of the court and jury and exceeding her relevant qualifications. *See, e.g.*, *Lloyd v. Johnson & Johnson*, No. BC628228 (JCCP No. 4872) (Cal. Super. Ct.) (Plaintiff Eva Echeverria only) ("Plunkett *Echeverria* Ruling") at 6 (precluding Dr. Plunkett "from opining that talc based powder should have been labelled to warn of the risks" because such an opinion is an improper "legal opinion") (Ex. 6 to Davidson Decl.); *id.* ("[A]lthough she may have taken courses on FDA matters and give[s] advice on same, she is not qualified to opine as to FDA regulations or their applicability to labeling."); *Newman by & through Newman v. McNeil Consumer Healthcare*, No. 10-1541, 2013 WL 9936293, at *5 (N.D. Ill. Mar. 29, 2013) (precluding Dr. Plunkett from testifying about whether defendants "met" regulatory requirements); *Tsao v. Ferring Pharms., Inc.*, No. 16-01724, 2018 WL 3649714, at *12, *14 (S.D. Tex. Apr. 19, 2018) (Dr. Plunkett's opinions that medication "was adulterated, misbranded, or false and misleading under the FDA and [FDCA] regulations" constituted "inadmissible legal

[9] (*Id.* ¶¶ 27, 105; *see also id.* ¶ 108 (relying on 21 C.F.R. § 740.1(a) in opining that "a warning about serious tissue toxicity and the increased risk of ovarian cancer with use of talcum powder products should have been included on the product labeling").)

conclusions.").

C. William Sage, M.D., J.D.

Dr. Sage is a law professor with supposed expertise "in the science of policymaking" and "regulatory design."[10] He had no experience in cosmetic-specific regulations before serving as an expert in this case.[11] Dr. Sage nonetheless seeks to opine on the "regulatory practices and standards" of the cosmetics industry and whether "Johnson & Johnson compl[ied] with th[ose] standards."[12] For example, Dr. Sage attempts to explicate the J&J defendants' duty to warn under 21 C.F.R. § 740.1(a) and tell jurors what (if any) ***legal*** impact the FDA's denial of the Citizens Petition Letter seeking a cancer warning had on that duty.[13]

At his deposition, Dr. Sage conceded that he is "not offering [an] independent professional assessment of causation," only conducted a "first pass review of the scientific literature" and did not do a Bradford Hill analysis—or any sort of formal methodological review—of the alleged talc/ovarian cancer

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10 (Am. Rep. of William Sage ("Sage Am. Rep.") ¶ 9, Nov. 15, 2023 (Ex. 7 to Davidson Decl.).)

11 (*Id.* ¶ 1; Dep. of William M. Sage ("9/23/21 Sage Dep.") 29:7-32:6, Sept. 23, 2021 (Ex. 8 to Davidson Decl.).)

12 (Sage Am. Rep. ¶ 11.)

13 (*Id.* ¶¶ 82-83; *see also id.* ¶¶ 85-99.)

association.[14] He nonetheless purports to offer "inferences about causation and risk and uncertainty based on other expertise from other individuals."[15]

D. George E. Newman, Ph.D.

Dr. George E. Newman is an "experimental psychologist" and marketing professor whose professional work, outside of teaching, consists of conducting experiments to understand consumer behavior and perceptions based on empirical data.[16] He challenges the J&J defendants' marketing of talcum powder products, which he claims "created confusion and misunderstanding among consumers."[17] Dr. Newman did not conduct any experiments and has no empirical data to support this hypothesis.[18] This is particularly troubling because, as an "experimental psychologist," Dr. Newman testified that he conducts experiments "to understand" "consumer perceptions."[19]

The remainder of Dr. Newman's report amounts to improper opinions on the

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14 (9/23/21 Sage Dep. 118:22-119:19, 120:10-122:3.)

15 (*Id.* 118:22-119:19; *see also* Sage Am. Rep. at App. 1.)

16 (Dep. of George Newman ("5/15/24 Newman Dep.") 39:19-42:7, May 15, 2024 (Ex. 9 to Davidson Decl.); Rep. of George Newman ("Newman Rep.") ¶ 1, Nov. 15, 2023 (Ex. 10 to Davidson Decl.).)

17 (Newman Rep. ¶ 98.)

18 (*See* 5/15/24 Newman Dep. 67:19-68:9, 71:24-72:1.)

19 (*Id.* 39:14-42:7; *see also id.* 207:11-24 (testifying that he always "provided experimental research to support [his] findings" in his published work that evaluates how consumers interpret and weigh information).)

J&J defendants' state of mind and narrative summaries of company documents. He frequently opines as to what J&J knew[20] and speculates as to J&J's motives for taking certain actions.[21] And Dr. Newman's report summarizes straightforward internal documents concerning J&J's development of a cornstarch-based replacement for its talcum powder products.[22]

ARGUMENT

The standards for the admission of expert testimony are set forth in detail in defendants' motion to exclude the general causation opinions of plaintiffs' experts, which is incorporated herein. All of the opinions being offered by Drs. Kessler, Plunkett, Sage and Newman fail to satisfy Rule 702 for multiple reasons.

I. DRS. KESSLER, PLUNKETT, SAGE AND NEWMAN OFFER A HOST OF IMPROPER "EXPERT" OPINIONS.

A. Drs. Kessler, Plunkett, Sage And Newman's Factual Narratives Do Not Constitute Proper Expert Testimony.

As this Court has recognized, an expert may not "simply rehash internal corporate documents" because such "opinions are not properly the subject of expert testimony." *O'Bryant v. Johnson & Johnson*, No. 20-2361, 2022 WL 7670296, at *13 (D.N.J. Oct. 13, 2022) (Shipp, J.) (testimony that "simply

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[20] (*See, e.g.*, Newman Rep. ¶ 15 ("[A]s early as the 1970s, Johnson & Johnson was aware of potential health hazards associated with talcum powder products.").)

[21] (*See, e.g.*, *id.* ¶ 54 (J&J "was motivated specifically by safety concerns regarding talc" in considering cornstarch as a replacement powder product).)

[22] (Newman Rep. ¶¶ 45-56, 58-65, 68-72.)

parrot[s] [d]efendant's corporate documents or offer[s] a narrative account of events from them will not be helpful to the jury") (citation omitted). Rather, "[s]uch testimony is properly presented through fact witnesses and documentary evidence." *Id.*; *see also In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008) ("[S]imply summariz[ing] a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony."), *aff'd in part, rev'd in part*, 586 F.3d 547 (8th Cir. 2009).

All four experts provide "opinions" that are inadmissible under this well-accepted principle.

- ***Dr. Kessler*** summarizes internal documents and testimony in Section II.C of his report, titled, "Defendants' statements that cosmetic manufacturers have responsibility to substantiate the safety of their product."[23] For example, Dr. Kessler repeatedly quotes straightforward statements from an internal J&J PowerPoint presentation concerning product safety: "In a June 24, 2003, PowerPoint, JNJ stated that Johnson's Baby products are 'assessed for safety based on the intended use.' JNJTALC000777136."[24] Similarly, his extensive discussion of the safety and geology of asbestos and purportedly positive findings of asbestos is merely a narrative of internal J&J documents and testimony and materials produced by talc supplier Imerys.[25] At no point does Dr. Kessler even attempt to analyze these materials; rather, he simply quotes them verbatim, such as an Imerys document purporting to address an "asbestos

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23 (*See, e.g.*, Kessler Am. Rep. ¶¶ 55-63.)

24 (*Id.* ¶¶ 57-61.)

25 (*See id.* ¶¶ 74-106.)

problem[].”[26] He does the same in Section VI.A, titled “JNJ recognized iconic nature of their product.”[27] And the majority of Section IV of his report consists of Dr. Kessler rehashing documents and, in turn, summarily concluding that talcum powder products are adulterated per 21 U.S.C. § 361.[28]

- ***Dr. Plunkett*** opines about what various “documents show” regarding the actions of defendants taken at various points in time and defendants’ motivations for taking those actions.[29] For example, in describing the J&J defendants’ supposed “efforts to influence the science around the issue of asbestos in talc and the link of talc with ovarian cancer,”[30] Dr. Plunkett simply quotes from a decades-old statement by a Johnson & Johnson employee to the then-FDA Commissioner.[31] Similarly, in challenging the safety of talc, Dr. Plunkett quotes from a 1964 J&J memo addressing cornstarch as an alternative.[32] And in a series of five full pages, Dr. Plunkett also quotes at length from “other internal corporate documents” that she claims support her opinion that the J&J defendants were “aware” of a potential “health hazard” posed by cosmetic talc, but omits any analysis of these materials, which jurors can interpret on their own.[33]

- ***Dr. Sage*** offers a historical summary of cherry-picked events based on internal documents that jurors can comprehend without expert testimony. For example, he seeks to tell jurors that “[i]n 1952 [J&J] submitted a patent application for a ‘nonirritating’ cornstarch alternative to talc” as support for his opinion that J&J “has known

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26 (*Id.* ¶ 88.1.)

27 (*Id.* ¶¶ 155-160 (quoting documents and deposition testimony for statements as straightforward as “classic Johnson’s Baby Powder fragrance is the most recognizable fragrance in the world”).)

28 (*Id.* ¶¶ 107-140.)

29 (*See, e.g.*, Plunkett 3d Am. Rep. ¶¶ 79, 84, 96, 98, 103, 104, 115, 118, 119.)

30 (*Id.* ¶ 79.)

31 (*Id.* (citation omitted).)

32 (*See id.* ¶ 111 (citation omitted).)

33 (*See id.* ¶ 115.)

about risk and uncertainty regarding talc and ovarian cancer for decades."[34] Similarly, in claiming that "Johnson & Johnson manipulated asbestos testing . . . so that 'none detectable' would be interpreted as 'none,'" Dr. Sage inappropriately offers his narrative of historical facts as well as J&J's internal and external communications.[35] And, in opining that the Cosmetic Ingredient Review ("CIR") "favor[s] industry interests," Dr. Sage summarizes lay communications between CIR and industry with no accompanying analysis as to how they demonstrate favoritism.[36]

- ***Dr. Newman*** seeks to describe what "[d]ocuments reviewed show" about the "potential health hazards associated with talcum powder products."[37] To that end, in four separate sections, Dr. Newman simply quotes and summarizes Dr. Daniel Cramer's 1982 study on talc, the 1994 and 2008 Citizens' Petitions to the FDA (and internal documents concerning the petitions), Health Canada's 2021 report, and the FDA's request to replace talc with cornstarch for surgical gloves and condoms.[38] To the extent Dr. Newman addresses marketing issues, he similarly regurgitates facts from straightforward documents concerning, for example, J&J's consideration of cornstarch as a replacement powder product,[39] J&J's marketing to particular demographics and so-called "super-heavy users" of Johnson's Baby Powder.

In all of these examples, Drs. Kessler, Plunkett, Sage and Newman

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34 (Sage Am. Rep. ¶¶ 51-61; *id.* at 8.)

35 (*Id.* ¶¶ 117-123, 125.)

36 (*Id.* ¶¶ 133-141; *id.* at 21.)

37 (*See, e.g.*, Newman Rep. ¶ 15; *see also id. id.* ¶ 97 (similar).)

38 (*Id.* ¶¶ 57, 73-74, 75-76, 82-83, 92.)

39 (*Id.* ¶¶ 45-47 (quoting internal memos and documents to provide a factual narrative of the initial steps purportedly taken to develop cornstarch as a replacement product allegedly in response to health risk); *id.* ¶¶ 48-56 (quoting and summarizing documents to show cornstarch was a feasible replacement); *id.* ¶¶ 58-65 (doing the same); *id.* ¶¶ 68-72 (quoting and summarizing documents that discussed mundane marketing and sales facts concerning cornstarch).)

improperly seek to parrot corporate documents or offer a narrative account of events, which "will not be helpful to the jury." *O'Bryant*, 2022 WL 7670296, at *13. Accordingly, these "lay" opinions do not constitute proper "expert" testimony and must be excluded under Rule 702.

B. Drs. Kessler, Plunkett And Sage's Regulatory Opinions Amount To Improper Legal Conclusions That Are Not The Proper Subject Of Expert Testimony.

The "prohibition on experts testifying as to their own legal conclusions is 'so well established that it is often deemed a basic premise or assumption of evidence of law'" that has been adopted by "every circuit." *Holman Enters. v. Fid. & Guar. Ins. Co.*, 563 F. Supp. 2d 467, 472 (D.N.J. 2008) (citations omitted) (striking expert report "replete with legal conclusions and speculations that ultimately render his entire report deficient"). As the Third Circuit has explained, such opinions are improper because they "interfere with the district court's 'pivotal role in explaining the law to the jury.'" *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013) (citation omitted).[40]

[40] *See also, e.g.*, *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 218 (3d Cir. 2006) (expert may not testify "as to what was required under the law, or whether the defendant complied with the [law]"); *United States ex rel. Silver v. Omnicare, Inc.*, No. 11-01326, 2023 WL 2808098, at *8-13 (D.N.J. Mar. 31, 2023) (excluding expert opinions that improperly explained "what the [Anti-Kickback Statute] prohibits," "venture[d] toward applying [defendant's] actual alleged actions to its identified legal duties," indicated that the facts "suggest" defendant "violated the [statute]," as well as portions of an expert report that "state[d] what is and is not a violation of the" statute); *Crockett v. Luitpold Pharms., Inc.*, No. 19-276, 2023 WL

Courts have precluded Drs. Plunkett and Kessler from offering legal opinions at trial based on these principles. For example, a court presiding over talcum powder cases in California barred Dr. Plunkett "from opining that talc based powder should have been labelled to warn of the risks" because such an opinion is an improper "legal opinion."[41] Another court precluded Dr. Plunkett from testifying about "what reporting requirements [d]efendants had under FDA regulations and whether [d]efendants ***met them***," noting that much of her testimony "consists of quoted portions of the [FDA] regulations themselves or descriptions of what the regulations require," which was "unnecessary," and risked jurors "mistakenly conclud[ing] that her opinion or conclusion is the law." *Newman by & through Newman*, 2013 WL 9936293, at *5 (emphasis added); *see also Tsao*, 2018 WL 3649714, at *12, *14 (excluding Dr. Plunkett's "opinions that Bravelle was adulterated, misbranded, or false and misleading under the FDA [and FDCA] regulations" because they constituted "inadmissible legal conclusions").

Similarly, in an antitrust case, a federal court held that Dr. Kessler could not provide the jury with numerous legal conclusions, including that the defendant's

2187641, at *3 (E.D. Pa. Feb. 23, 2023) (excluding expert testimony that labeling laws were "improperly followed" or that "failures to update the labeling, rendering it false & misleading . . . meets the definition of the regulatory term 'misbranded'") (citation omitted).

41 *See* Plunkett *Echeverria* Ruling at 6.

submission to the FDA "violated the law, constituted fraud on the FDA, or was otherwise improper" and that the defendant's requested "labeling change . . . would violate the law." *In re Prograf*, 2014 WL 7641156, at *1-2. As the court explained, such testimony would not constitute proper expert testimony because "Dr. Kessler is not—and, indeed, cannot be—a legal expert. It is for the court alone to instruct the jury on what the law is." *Id.* at *2.

Despite these principles and precedents, Drs. Kessler, Plunkett and Sage all seek to offer improper legal opinions in this litigation.

- ***Dr. Kessler*** opines that the J&J defendants violated legal standards by failing to "substantiate the safety of their talcum powder products."[42] He further asserts that "JNJ was required to place the following conspicuous statement on the principal display panel: 'Warning – The safety of this product has not been determined.' 21 C.F.R. § 740.10."[43] And he testifies that J&J's talcum powder products were contaminated with asbestos and therefore "adulterated" under 21 U.S.C. § 361.[44]

- ***Dr. Plunkett*** includes in her report an entire section titled "Talcum Powder Products: The Regulatory Process" where, among other things, she specifies FDA regulations and juxtaposes those applicable to cosmetic manufacturers and those that govern drug manufacturers.[45] She opines that "unlike drugs, cosmetics are expected to carry warnings based on a standard of a ***possibility*** of health hazard."[46] Dr. Plunkett also asserts that the J&J defendants

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42 (*Id.* §§ III- IV; *id.* ¶¶ 106, 154, 232.)

43 (*Id.* ¶ 106; *see also id.* ¶¶ 68-69.)

44 (*Id.* ¶ 139.)

45 (*See* Plunkett 3d Am. Rep. ¶¶ 15-27.)

46 (*Id.* (emphasis added).)

"failed to properly substantiate and ensure the safety of their cosmetic body powder products" and, as such, "should have warned consumers about the toxic constituents [of their talc products], such as asbestos, fibrous talc, cobalt, nickel, and chromium," as well as provided a label that "warn[ed] of the risk of ovarian cancer."[47] Dr. Plunkett further opines that these alleged failures rendered Johnson's Baby Powder an "adulterated product."[48]

- ***Dr. Sage*** opines that the J&J defendants "marketed and sold a misbranded and adulterated product,"[49] that they did not substantiate, "establish[,] or maintain the safety of [their] talcum powder products,"[50] and that they failed to provide legally required warnings of possible hazards associated with talcum powder.[51] Dr. Sage also claims that the FDA's denial of the Citizens Petition Letter did not discharge the J&J defendants' duty to warn under 21 C.F.R. § 740.1(a), and that defendants cannot meet a legal exception to avoid disclosure of the risks of talc under 21 C.F.R. § 740.10(b) because "not a single part of the three-part test for an exception to disclosure . . . has been met."[52]

As these examples illustrate, Drs. Kessler, Plunkett and Sage repeatedly seek to opine that the J&J defendants violated the law—e.g., that Johnson's Baby Powder was "adulterated" or "misbranded"—which are "inadmissible legal

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47 (*Id.* ¶¶ 105, 108, 121-123.)

48 (*Id.* ¶ 123.) All of these regulatory opinions are separately impermissible since they far outstrip Dr. Plunkett's expertise. As the *Echeverria* court recognized, "although she may have taken courses on FDA matters and give[s] advice on same, she is not qualified to opine as to FDA regulations or their applicability to labeling." Plunkett *Echeverria* Ruling at 6.

49 (Sage Am. Rep. ¶¶ 37-44, 181.)

50 (*Id.* ¶¶ 83, 176.)

51 (*Id.* ¶¶ 48, 82-83, 178-179.)

52 (*Id.* ¶¶ 82-83; *see also id.* ¶¶ 85-99.)

conclusions." *Tsao*, 2018 WL 3649714, at *12, *14. But "[i]t is the jury's job to determine whether [defendant's] conduct violated the [law] . . . not the expert's," *Allscripts Healthcare, LLC v. Andor Health, LLC*, No. 21-704, 2022 WL 3021560, at *27 (D. Del. July 29, 2022). Because Drs. Kessler, Plunkett and Sage's legal conclusions contravene these principles, they should be excluded under Rule 702.

C. Drs. Kessler, Plunkett, Sage And Newman's Opinions Regarding Defendants' State Of Mind Do Not Constitute Admissible Expert Evidence.

This Court has made clear that experts cannot opine on "the state of mind or culpability of [d]efendants." *O'Bryant*, 2022 WL 7670296, at *12 (citation omitted) (excluding expert opining on defendants' "knowledge and state of mind (i.e., whether [defendants were] 'misleading' and what [defendants] knew at the time)" and collecting cases holding the same); *see also Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 440 (D.N.J. 2009) (striking expert who "purported to divine what [the defendant] was 'trying' to do with its marketing strategy and what it believed was right or wrong"). This is so because "the question of intent constitutes a 'classic[] jury question and not one for experts.'" *Krys v. Aaron*, 112 F. Supp. 3d 181, 203 (D.N.J. 2015) (citations omitted).

Courts have excluded improper state-of-mind opinions offered by Drs. Kessler and Plunkett under these principles. For example, the *Prograf* court

precluded Dr. Kessler from opining as to "why [defendant] or anyone else acted as they did" or offering "personal opinion testimony about [defendant's] knowledge, intent, or motives." 2014 WL 7641156, at *2. Similarly, in *Echeverria*, the court barred Dr. Plunkett from testifying that "defendants downplayed the risks of talc and actively determined not to tell consumers of them."[53] As the court recognized, "[t]his testimony [was] based solely on reading documents . . . and then opining as to the mental state of individuals in the corporation."[54] "This is not permissible," the court explained, because "expert testimony is not needed on this subject."[55]

All four experts repeatedly offer this sort of improper "expert" testimony. For example:

- ***Dr. Kessler*** opines that "[J&J] was aware that false negative results would occur with its testing methodology"[56] and that J&J "had concerns regarding asbestos and the safety of its product."[57] He also claims that J&J "***decided*** in the 1970's to aggressively defend its product. That strategy . . . put the public's health at risk. It need not have been that way ***if JNJ was willing*** to bear any additional cost and reformulate the product."[58]

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53 Plunkett *Echeverria* Ruling at 6.

54 *Id.*

55 *Id.* at 6-7.

56 (Kessler Am. Rep. ¶ 201.)

57 (*See id.* § VI.B.)

58 (*Id.* ¶ 188 (emphasis added); *see also id.* § VI.K (J&J's "approach to the asbestos issue in talc was to initiate studies only as required by confrontation"); *id.* § VI.L, ¶ 235 (describing J&J's "defensive strategy of creating doubt and confusion" "when the safety of their product was brought into question").)

- ***Dr. Plunkett*** opines on what the J&J defendants "knew or should have known" about the purported risks posed by talc and when.[59] She testified that J&J should have added "a warning to their product based on what they knew many, many, many years ago, back in the . . . 1930s, '40s, and '50s."[60] She also speculates about defendants' intent and motive, claiming that "[d]ocuments from" the 1970s "show that the ***goal*** was to mount a defense strategy around talc and to ensure that the products continued to be sold without regulation."[61] Similarly, Dr. Plunkett opines that "industry had no interest in sponsoring any new research or did not want to spend the money on such research" based solely on her "review of . . . depositions and documents."[62]

- ***Dr. Sage*** opines that "Johnson & Johnson has known about risk and uncertainty regarding talc and ovarian cancer for decades."[63] Dr. Sage also addresses J&J's "stated corporate intent," "[J&J's] communications as it learned various types of scientific information," and "[J&J's] resistance to testing."[64] For example, Dr. Sage challenges J&J's alleged "lack of interest in finding out current scientific fact about its products";[65] J&J's "apparent uninterest . . . in

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59 (*See, e.g.*, Plunkett 3d Am. Rep. ¶ 78 ("Johnson & Johnson knew or should have known that use of cosmetic talc body powders had been reported to lead to lung injury when the talc was inhaled . . . ."); *id.* ¶ 104 ("[D]efendants were aware of the human health hazards associated with talc powder products for many decades."); *id.* ¶ 115 (providing a bulleted summary of internal documents that "support [Plunkett's] opinions that the defendants were aware that talcum powder products may be associated with a health hazard").)

60 (12/21/23 Plunkett Dep. 136:16-24.)

61 (Plunkett 3d Am. Rep. ¶ 96 (emphasis added) (citations omitted).)

62 (*Id.*)

63 (Sage Am. Rep. at 8; *see also id.* ¶ 176 ("Johnson & Johnson knew its products contained carcinogens, including asbestos, fibrous talc, and heavy metals.").)

64 (Dep. of William M. Sage ("4/1/24 Sage Dep.") 39:23-41:7, Apr. 1, 2024 (Ex. 11 to Davidson Decl.).)

65 (*Id.* 48:12-24.)

supporting more detailed or definitive studies over the decades";[66] and J&J's "persistent unwillingness . . . to make any concession whatsoever regarding the lack of evidence of safety for its legacy product."[67]

- ***Dr. Newman*** also seeks to opine on the J&J defendants' mental state—delineating what J&J "promised"[68]; what J&J "was aware of"[69]; and what "motivated" J&J.[70] Moreover, at his deposition, Dr. Newman expressly agreed that it is his opinion that "Johnson & Johnson in the eighties decided, never mind, we're going to continue marketing talc even though ***we think*** there's a credible risk of cancer with its use and even though we have an effective replacement that our market data suggests consumers prefer."[71]

As the above examples make clear, Drs. Kessler, Plunkett, Sage and Newman repeatedly "read[] documents . . . and then opin[e] as to" defendants' state of mind—which is not "not permissible."[72]

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66 (9/23/21 Sage Dep. 366:2-17.)

67 (*Id.* 301:8-21.)

68 (Newman Rep. ¶ 12 ("Johnson & Johnson promised to prioritize the health and well-being of their customers above all else.").)

69 (*Id.* ¶ 15 ("[A]s early as the 1970s, Johnson & Johnson was aware of potential health hazards associated with talcum powder products."); *see also id.* ¶¶ 16, 24, 65, 97 (similarly claiming, based on a review of the record, what things J&J "was aware of," and how J&J "regarded" them).)

70 (*See, e.g.*, *id.* ¶ 54 (stating J&J's decision to conduct market research on cornstarch "was motivated specifically by safety concerns regarding talc"); *id.* ¶ 19 (opining that J&J "sought to compensate for declining sales of talcum powder products by targeting specific demographics of consumers"); 5/15/24 Newman Dep. 81:22-83:15 (opining J&J developed cornstarch as a replacement because of the "concerns about talcum powder"); 5/15/24 Newman Dep. 94:8-10 (same).)

71 (5/15/24 Newman Dep. 95:6-14 (emphasis added).)

72 Plunkett *Echeverria* Ruling at 6-7.

D. Drs. Kessler, Plunkett, Sage And Newman's Opinions Concerning Defendants' Ethical Responsibilities Should Be Excluded.

The four experts also repeatedly opine on defendants' ethics, which is not a proper subject of expert testimony, is irrelevant and is unfairly prejudicial and confusing.

First, testimony "concerning the ethical obligations of . . . companies and whether the defendants' conduct was ethical [is] inadmissible" because it rests on "personal, subjective views" rather than "knowledge" within the meaning of Rule 702. *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 542-43 (S.D.N.Y. 2004); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1057-58 (D. Minn. 2007) (excluding expert testimony that "Bayer was unethical" because "[p]ersonal views on corporate ethics and morality are not expert opinions"). Indeed, courts in this circuit make clear that "subjective views of ethics [even if] informed by well-known principles does not convert them into objective, reliable, scientific knowledge." *See Wolfe v. McNeil-PPC, Inc.*, No. 07-348, 2011 WL 1673805, at *8-9 (E.D. Pa. May 4, 2011) (holding expert testimony that defendant had a "'responsibility' to develop a better warning . . . and better communicate the risks of their product are not based on reliable methodology").

Drs. Kessler, Sage, Plunkett and Newman violate this principle in offering subjective testimony as to the ethical appropriateness of the J&J defendants' actions. For example, Dr. Kessler repeatedly opines that J&J failed to conduct

itself as a "reasonable and prudent company" in various respects.[73] As an illustration, he opines that "a reasonable and prudent company would attempt to improve the sensitivity of its testing" for asbestos, which J&J purportedly did not do.[74] Dr. Plunkett states that "in my view, there was influence [from J&J] that I don't think, in my view, was -- was appropriate in terms of what I would tell my clients to do in their interactions with -- with the FDA."[75] Dr. Sage similarly opines that J&J "did not engage in the type of responsible corporate behavior in a voluntary system that I would like to see a company do."[76] And Dr. Newman states that the J&J defendants violated what he teaches as "best practices" in not disclosing even a "glimmer of a possibility" of a health risk associated with talcum powder products.[77] Nowhere in the above examples do these experts reference any objective standard—industry or otherwise—making clear that these opinions are not grounded in any reliable scientific methodology.[78]

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73 (Kessler Am. Rep. ¶¶ 189, 201, 214, 222, 250.)

74 (*Id.* ¶¶ 201-202.)

75 (Dep. of Laura M. Plunkett ("8/10/21 Plunkett Dep.") 217:20-24, Aug. 10, 2021 (Ex. 12 to Davidson Decl.).)

76 (9/23/21 Sage Dep. 368:2-11; *see also* 4/1/24 Sage Dep. 114:7-12 ("I can assume that at some point in Johnson & Johnson's corporate history, it attempted to behave responsibly with respect to both testing and the use of testing. But I have seen nothing to indicate that that was a consistent practice . . . .").)

77 (5/15/24 Newman Dep. 118:2-119:22.)

78 Dr. Kessler's experience as a former FDA commissioner does not salvage his claims about defendants' ethics. As another court in this circuit explained,

Drs. Sage and Kessler stray even further outside the boundaries of Rule 702 by inappropriately commenting on how they ***felt*** about defendants' behavior. Dr. Sage testified that he found J&J's statements on "Facts About Talc" to be "disappointing, frankly shocking"[79] and that J&J's failure to disclose risks was "very disturbing" and left him "really shocked."[80] Dr. Kessler opines that J&J's claims that its product was "asbestos free" without sufficiently "vigorous efforts to improve" testing was "concerning."[81] Such subjective statements are also not rooted in any reliable principle or methodology. *See Ruberti v. Ethicon, Inc.*, No. 20-874, 2021 WL 5570109, at *10 (M.D. Ala. Nov. 29, 2021) ("not appropriate for [expert] to assert that [d]efendants' behavior is 'disturbing'" as it is not "the kind of statement that can be based on reliable principles and methodology'").

Second, Drs. Sage and Newman's opinions that the J&J defendants failed to adhere to J&J's company "credo,"[82] or made representations "[c]ontrary to [J&J's]

"ethical standards for [pharmaceutical] companies do not come from the FDA" and as such, barred an expert on FDA procedures from opining on the "ethical standards a reasonable pharmaceutical company should follow." *Bartoli v. Novartis Pharms. Corp.*, No. 13-0724, 2014 WL 1515870, at *6 (M.D. Pa. Apr. 17, 2014).

79 (9/23/21 Sage Dep. 302:2-7.)

80 (*Id.* 314:2-19.)

81 (Kessler Am. Rep. ¶ 210.)

82 (5/15/24 Newman Dep. 98:21-99:20 (testifying that J&J's failure to switch to cornstarch ran contrary to the "credo of the company" because "[t]he credo isn't

representations regarding ethics"[83] are separately inadmissible as irrelevant. While these claims are purportedly tethered to a standard other than the experts' personal views, the fact remains that the J&J defendants' legal obligations control, not their internal ethics policies. *See In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2436, 2016 WL 807377, at *8 & n.22 (E.D. Pa. Mar. 2, 2016) (holding that an expert's "use of the Johnson & Johnson Credo to show 'standard of care' would . . . be inappropriate" even if there is a negligent marketing claim; "The defendants' own Credo should not be held out as the legal standard by which it should conduct its affairs"); *In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, at *9 (E.D. Pa. Feb. 1, 2001) (excluding "medical ethics" expert because the proposed testimony was "only marginally relevant" to "the manufacturing and marketing of diet drugs" where the "pertinent issues . . . are the obligations of a pharmaceutical company in testing, surveying and labeling medications"). This is so because "ethics testimony" does "not assist the fact-finder in determining any factual dispute" in a product liability case. *In re Rezulin*,

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like, your health and safety is number one, unless it has negative economic repercussions for us").)

[83] (Sage Am. Rep. at 19 ("Contrary to its representations regarding ethics and compliance, [J&J] has resisted or suppressed testing and standards for testing talc-based products instead of encouraging them."); *see also* 4/1/24 Sage Dep. 41:17-24 (taking issue with "this protracted resistance by [J&J] to honoring its legal and corporate ethical obligations to be forthcoming with the public about the risks of talcum powder").)

309 F. Supp. 2d at 544. As one court put it, "[w]hile the defendants may be liable in the court of public opinion, or before a divine authority for any ethical lapses, expert opinion as to the ethical character of their actions simply is not relevant to these lawsuits." *Id.*

Third, even assuming these ethics opinions were the product of reliable methods and were marginally relevant, any probative value would be "vastly outweighed by the tendency of such testimony to encourage the jury to impose liability on an improper basis" and are inadmissible under Rule 403. *Wolfe*, 2011 WL 1673805, at *9 (expert's testimony about defendant's "social responsibility and ethical obligations" was alternatively inadmissible under Rule 403). As previously discussed, these opinions boil down to gratuitous accusations that defendants engaged in "shocking" and "very disturbing" conduct, which would merely play to the emotions of jurors rather than elucidate the complex scientific questions that require expert testimony in this litigation.

II. DR. NEWMAN'S MARKETING OPINIONS AND DRS. PLUNKETT'S AND SAGE'S CLAIMS ABOUT THE SAFETY OF TALC ARE NOT BASED ON A RELIABLE METHODOLOGY.

Dr. Newman's marketing opinions and Drs. Plunkett and Sage's claims regarding the purported relationship between cosmetic talc and ovarian cancer are not based on any reliable methodologies and are separately inadmissible.

"[N]othing in either *Daubert* or the Federal Rules of Evidence requires a

district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Accordingly, the Third Circuit has long held that an expert who has "employed absolutely no methodology at all" cannot offer reliable testimony at trial. *See Scrofani v. Stihl Inc.*, 44 F. App'x 559, 561-62 (3d Cir. 2002) (affirming exclusion of expert who "employed absolutely no methodology at all," merely setting forth "a series of unsubstantiated opinions") (citation omitted). That principle is all the more clear in light of the recent amendments to Rule 702. *See In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, MDL No. 3043, 2024 U.S. Dist. LEXIS 121259, at *44 (S.D.N.Y. July 10, 2024) (granting motion to exclude and explaining that "conclusions and methodology are not entirely distinct from one another") (quoting *Joiner*, 522 U.S. at 146). Dr. Newman's marketing opinions and the safety-related opinions being offered by Drs. Plunkett and Sage violate these principles.

A. Dr. Newman's Marketing Opinions Are Unreliable.

Expert testimony about the effect or impact of a marketing strategy must be supported by "hard evidence," such as "citations to public opinion surveys, anthropological, market or sociological studies" or other evidence "that would demonstrate the actual impact of . . . advertising." *Insolia v. Philip Morris Inc.*, 53 F. Supp. 2d 1032, 1041 (W.D. Wis. 1999) (excluding marketing expert's

"sweeping assertions" that tobacco industry's advertising caused consumers to underappreciate the risks of smoking absent citations to surveys, market studies), *aff'd in part, rev'd in part on other grounds*, 216 F.3d 596 (7th Cir. 2000); *accord Bracco*, 627 F. Supp. 2d at 439 (excluding marketing expert's opinions regarding "customers' supposed expectations of pharmaceutical advertising" in part because the expert "did not conduct or rely on any official customer survey for his opinions . . . .") (citation omitted); *see also Montera v. Premier Nutrition Corp.*, No. 16-06980, 2022 WL 1225031, at *5-6 (N.D. Cal. Apr. 26, 2022) (permitting expert to opine on "marketing principles" but excluding "testimony concerning how consumers ***interpreted*** the intended message[s]" because the expert "provide[d] little support for his opinion on how consumers actually interpreted" them) (emphasis added).

Here, Dr. Newman's marketing opinions are not grounded in any hard evidence. While Dr. Newman purports to rely on J&J's internal market research to demonstrate that J&J successfully cultivated "trust" with its consumers, he conceded that he has no empirical data demonstrating that such trust actually affected consumers' perceptions of the safety of talc.[84] He nonetheless sought to

[84] (Newman Rep. ¶ 99; 5/15/24 Newman Dep. 65:21-67:24.) While Dr. Newman stated that he ran his own undisclosed "pilot study" to inform himself on some issues, he made clear he was not relying on this undisclosed study in any way. (5/15/24 Newman Dep. 67:19-72:1.)

substantiate his claims by repeatedly referencing a study involving Coke, that supposedly shows how brand awareness can affect consumer perception.[85] In that study, consumers reported that they preferred Coke over Pepsi despite not being able to tell them apart in a blind taste test.[86] While Dr. Newman speculated that "I think that's also true" "in this case,"[87] he also made clear that—unlike here—there was "empirical evidence, experimental studies" to support the conclusions regarding branding.

Dr. Newman's other overarching claim that the J&J defendants "engaged in misleading and deceptive conduct" in marketing talcum powder products is similarly speculative.[88] He claims that defendants' purported misrepresentations "created confusion and misunderstanding among consumers" about talc's alleged health risks."[89] For example, Dr. Newman opines that ***the way*** the website—"factsabouttalc.com"—discusses the epidemiological studies is misleading because "it's a very complicated sentence" and J&J is "burying the lead" in presenting the information in a "confusing" way.[90] But this is pure conjecture; Dr. Newman did

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85 (5/15/24 Newman Dep. 39:8-13, 67:8-15, 217:10-218:7.)

86 (*Id.*)

87 (*Id.* 67:8-15.)

88 (Newman Rep. ¶ 98.)

89 (*Id.*)

90 (5/15/24 Newman Dep. 196:4-198:12.) This opinion represents a departure from his report, where Dr. Newman claimed that the website failed to address the

not "think [he] needed to run a study to confirm that fact."[91] The same is true of Dr. Newman's claim that J&J misled consumers in not communicating its decision-making process with respect to cornstarch as an alternative to talc.[92] Dr. Newman conceded that he has no idea why J&J did not replace talc with cornstarch,[93] and his opinion that it was misleading to not divulge this information is not based on any concrete evidence.

Dr. Newman's standardless opinions are particularly troubling because they are contrary to how he conducts his professional work outside the courtroom. *See Sakolsky v. Genie Indus.*, No. 15-6893, 2021 WL 3661398, at *8 (D.N.J. Aug. 18, 2021) (excluding expert in part given the expert was not "being as careful as he would in his professional work outside of . . . litigation") (citation omitted); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (*Daubert* requires that an expert "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). As an "experimental psychologist," Dr. Newman testified that "to understand" "consumer perceptions"

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epidemiological studies that found an association. At his deposition, he recognized that the website ***does*** in fact discuss those studies. (*Id.* 194:9-196:5.)

91 (*Id.* 197:9-14.)

92 (*Id.* 114:19-25 ("[T]he misleading or deceptive part is that the company has very deliberately taken a strategy to address the health concerns [of talc] through product replacement, and then that replacement never happens and the reason for it isn't communicated . . . .").)

93 (5/15/24 Newman Dep. 115:1-6.)

he conducts experiments.[94] Dr. Newman's stark departure from how he normally conducts his professional work reinforces the unreliability of his marketing opinions and strongly suggests that they were formulated for purpose of litigation.

Finally, even assuming Dr. Newman's failure to follow his own stated methodology could be excused, his marketing opinions would still not "help the trier of fact to understand the evidence or to determine a fact in issue," Fed. R. Evid. 702(a), and thus do not "fit" the facts of the case. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993); *see also Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 527 (W.D. Pa. 2003) ("The 'fit' requirement stems from the instruction of Federal Rule of Evidence 702 that proffered expert testimony must 'assist . . . the trier of fact.'"). After all, Dr. Newman does not even attempt to tether his opinions to marketing that any individual plaintiff actually viewed. Moreover, Dr. Newman's opinions regarding factsabouttalc.com could not have any relevance to the bellwether plaintiffs' claims since the website was created years after those individuals allegedly used defendants' talcum powder products. For this reason, too, his opinions should be excluded.

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[94] (*Id.* 39:14-42:7; *see also id.* 207:11-24 (testifying that he always "provided experimental research to support [his] findings" in his published work that evaluates how consumers interpret and weigh information).)

B. Drs. Sage And Plunkett's Epidemiology-Based Opinions Are Unreliable.

While Drs. Sage and Plunkett do not claim to have performed Bradford Hill analyses—the generally accepted methodology used by epidemiologists to evaluate the relationship between an alleged toxin and a disease—their reports are replete with opinions about general causation. As discussed below, because these opinions are not the product of a reliable methodology, they are inadmissible.

Dr. Sage. Dr. Sage (an out-of-practice anesthesiologist and current professor) attempts to "mak[e] supportable inferences about causation and risk and uncertainty based on other expertise from other individuals."[95] However, an "[e]xpert[] may not simply 'parrot' the ideas of other experts and should not 'become the mouthpiece of the witness on whose statements the expert purports to base his opinion.'" *Torain v. City of Philadelphia*, No. 14-1643, 2023 WL 174952, at *5 (E.D. Pa. Jan. 12, 2023) (citation omitted). This is so because Rule 703 "contemplates that a testifying expert can 'validate the facts, data and opinions he relied upon . . . and be subject to cross-examination on them.'" *Muhsin v. Pac. Cycle, Inc.*, No. 2010-060, 2012 WL 2062396, at *4, *8 (D.V.I. June 8, 2012) (citation omitted).

[95] (9/23/21 Sage Dep. 118:22-119:19; *see also* Sage Am. Rep. at App. 1.)

Dr. Sage admitted that he only conducted a "first pass review of the scientific literature" and did not do a Bradford Hill analysis—or any sort of formal methodological review—of the literature pertaining to the alleged talc/ovarian cancer association.[96] As such, Dr. Sage's ruminations about general causation are untethered to ***any*** discernible methodology and must be excluded. *See, e.g.*, *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, No. 10-143 et al., 2013 WL 3487560, at *14, *22 (W.D. Pa. July 12, 2013) (excluding expert testimony because expert's "failure to apply the Bradford Hill criteria, which he has called the 'gold standard' in this field, . . . is significant"); *Rimbert v. Eli Lilly & Co.*, No. 06-0874, 2009 WL 2208570, at *14 (D.N.M. July 21, 2009) (excluding expert testimony because "the Hill criteria are generally accepted" but the expert "inexplicably did not apply the Hill criteria to reach or test any of the conclusions in her report"), *aff'd*, 647 F.3d 1247 (10th Cir. 2011); *see also Scrofani*, 44 F.

[96] (9/23/21 Sage Dep. 119:8-15; *id.* 120:10-21 ("Q. You did not do a Bradford Hill analysis with regard to talcum powder use and ovarian cancer, right? A. I did not. . . . Q. You did not do a formal risk assessment with regard to talcum powder use and ovarian cancer, correct? A. I certainly didn't do a formal risk assessment."); *id.* 125:17-21 (conceding he had "not analyzed all the animal studies on talcum powder use and ovarian cancer"); *id.* 130:11-18 ("[Q.] You did not, as part of your methodology in this case, go out and search across all the medical and scientific literature to make sure you had found all of the epidemiologic studies looking at talcum powder use and ovarian cancer? A. As I said before, I did not do a PubMed search.").)

App'x at 561-62 (affirming exclusion of expert because he "employed absolutely no methodology at all").

Dr. Plunkett. Dr. Plunkett seeks to opine that genital exposure to talc increases the risk of ovarian cancer,[97] but her opinion is not the product of a reliable methodology either. As courts have recognized, an expert's opinions are inadmissible if the expert failed to faithfully apply her own analytical framework. *In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, MDL No. 3043, 2023 U.S. Dist. LEXIS 224899, at *100-01 (S.D.N.Y. Dec. 18, 2023) (excluding opinion because while the proffered methodology "is intended to be used by teams to minimize bias in the evaluation of the evidence . . . Dr. Baccarelli performed the analysis by himself"); *see also K.E. v. GlaxoSmithKline LLC*, No. 14-1294, 2017 WL 440242, at *15 (D. Conn. Feb. 1, 2017) (excluding expert opinion as unreliable where expert "did not 'apply his own methodology reliably'") (citation omitted).

Dr. Plunkett purports to have based her conclusion that genital exposure to talc increases the risk of ovarian cancer on a risk assessment analysis.[98] While such an analysis is itself a generally accepted method for determining risk, Dr. Plunkett did not reliably perform that analysis. As Dr. Plunkett testified, a human

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97 (*See* Plunkett 3d Am. Rep. ¶ 76.)

98 (*Id.* ¶ 11.)

health risk assessment is conducted in "four basic steps: hazard identification, dose-response assessment, exposure analysis, and characterization of risks (NRC, 1983)."[99] However, these steps do ***not*** purport to read causation out of the inquiry. To the contrary, and as the authorities she cites in her report make clear, in order to identify a hazard (i.e., the first step in a risk assessment), a scientist must first determine whether a particular toxin is causally linked to certain health effects.[100] In addition, the EPA—which Dr. Plunkett cites as an authoritative regulatory body with respect to risk assessment[101]—indicates in its Guidelines for Carcinogen Risk Assessment that the hazard identification step of risk assessment must include a critical assessment of evidence of causality and that "it is appropriate to draw from those aspects initially presented in Hill's classic monograph (Hill, 1965) and widely used by the scientific community in conducting such evidence-based reviews."[102]

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99 (*Id*.)

100 National Research Council, *Risk Assessment in the Federal Government: Managing the Process* 3 (1983), https://www.ncbi.nlm.nih.gov/books/NBK216620/pdf/Bookshelf_NBK21662 (cited in Plunkett 3d Am. Rep. ¶ 11) (defining hazard identification as "[t]he determination of whether a particular chemical is or is not causally linked to particular health effects").

101 (Plunkett 3d Am. Rep. ¶ 13.)

102 Risk Assessment Forum, U.S. Environmental Protection Agency, EPA/630/P-03/001F, *Guidelines for Carcinogen Risk Assessment* 2-11 (Mar. 2005), https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

Dr. Plunkett did not attempt to do that; indeed, she made clear that she did not perform a general causation analysis—much less a Bradford Hill analysis—in reaching her opinion that talc increases the risk of ovarian cancer.[103] Dr. Plunkett's exclusion of a causation analysis (and the Bradford Hill criteria for causation) as part of a risk assessment contradicts generally recognized scientific approaches, including those outlined in the authorities she herself cites. In short, Dr. Plunkett's failure to evaluate causation as part of her risk assessment contravened generally accepted methods, and her so-called risk assessment should be excluded.

III. DR. KESSLER'S ASBESTOS TESTING AND GEOLOGICAL OPINIONS FALL FAR OUTSIDE HIS AREA OF EXPERTISE.

Dr. Kessler also seeks to offer opinions on topics that far exceed his area of expertise, including asbestos testing methods, testing results and geology.

"Before an expert witness may offer an opinion pursuant to Rule 702[,] he must first be qualified by virtue of specialized expertise." *Ortiz v. Yale Materials Handling Corp.*, No. 03-3657, 2005 WL 2044923, at *3 (D.N.J. Aug. 24, 2005) (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)). "If an expert's area of experience 'is adjacent to, but not actually encompassing, the subject matter of his testimony, he may be deemed unqualified.'" *D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, No. 03-1026, 2006 WL 755984, at *3 (D.N.J. Mar.

[103] (12/21/23 Plunkett Dep. 92:7-13; Dep. of Laura M. Plunkett ("12/19/18 Plunkett Dep.") 33:22-35:21, Dec. 19, 2018 (Ex. 13 to Davidson Decl.).)

20, 2006) (citation omitted); *see also, e.g.*, *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321-23 (3d Cir. 2003) (citation omitted) (affirming limitations on the scope of expert testimony to ensure experts did not stray beyond scope of expertise that "require[d] more specific knowledge"); *see also Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1055 (3d Cir. 1997) (affirming that mechanical engineer was unqualified to opine on a machine's warning device because he had "no training and no experience" on "habituation" and had no "experience in designing equipment from a human safety standpoint").

Here, Dr. Kessler offers a variety of asbestos-related opinions that exceed the realm of his expertise.[104] For example, Dr. Kessler opines that J&J's talc products contained asbestos; he challenges the adequacy of industry asbestos testing; and he addresses the supposed geological formation of asbestos in the Vermont talc mines.[105] But Dr. Kessler is not a mineralogist, geologist, or microscopist—i.e., the specialists who are actually credentialed to opine on these complex subjects.[106] He has never tested talc or any other material for the presence of asbestos; nor was he familiar with the details of any talc testing methods before

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104 (*See* Kessler Am. Rep. ¶¶ 80-140, 161-168.5, 201-202.6.)

105 (*See* Dep. of David A. Kessler ("4/8/24 Kessler Dep.") 109:7-15, 113:3-25, 283:1-20, Apr. 8, 2024 (Ex. 14 to Davidson Decl.).)

106 (*Id.* 75:19-77:25.)

being retained as an expert in this litigation.[107] When asked "[w]hat basic principles did you understand before 2016 about the chemical and geological relationship between talc and asbestos," he testified about his "general understanding of geology" and that he "come[s] from a place that had a very strong geology history." According to Dr. Kessler, "some of the great geologists of the prior two centuries" taught where he went to college, though he did ***not*** take their courses.[108] And in offering the opinion that the peer-reviewed asbestos testing method J&J chose to use masked the presence of asbestos, he testified that he was not basing that opinion on any expertise in mineralogy or microscopy, but rather on his "ability to count."[109]

Notably, Dr. Kessler expressly recognizes his lack of expertise on these topics. As Dr. Kessler admitted, "[c]ertainly, other experts should testify, I mean, on the geology, mineralogy, and microscopy aspects. I do not want to get involved."[110] This, too, requires exclusion of his opinions. *See Ely v. Cabot Oil & Gas Corp.*, No. 09-2284, 2016 WL 4169220, at *6 (M.D. Pa. Feb. 17, 2016) (excluding testimony "[o]n the basis of this testimony alone—a string of admissions by Mr. Rubin that he is unqualified to opine on health, toxicological,

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107 (*Id.* 73:1-77:25.)

108 (*Id.* 74:20-75:22.)

109 (*Id.* 283:1-20.)

110 (*Id.* 76:3-22.)

and other harms presented by alleged constituents in the plaintiffs' water supplies").

CONCLUSION

For the foregoing reasons, the J&J defendants respectfully request that the Court exclude Drs. Kessler, Plunkett, Sage and Newman's opinions in full.

Dated: July 23, 2024

Respectfully submitted,

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